



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Predicting Patient Response to Cancer Therapy Via Histopathology Images

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Australian National University (“ANU”), a non-profit research institution located in Canberra, Australia for NCI’s rights to the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE *FEDERAL REGISTER*] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Kevin Chang, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, at: e-mail: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to ANU: United States Provisional Patent Application No. 63/349,829, filed June 7, 2022, entitled

“PREDICTING PATIENT RESPONSE TO CANCER THERAPY VIA
HISTOPATHOLOGY IMAGES” (HHS Ref. No. E-186-2022-0-US-01).

The Government of the United States of America and ANU are assignees of the patent rights in these inventions. The prospective license will be for the purpose of consolidating NCI’s patent rights to ANU, co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective patent license territory will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by ANU will be subject to the provisions of 37 CFR part 401 and 404.

This technology discloses a computational based method to predict whether a cancer patient will respond to targeted and immunotherapies against cancer using hematoxylin and eosin (H&E) slides from the patient’s tumor.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and

objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 1, 2023.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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